

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

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UNITED STATES OF AMERICA, :
 : Case No. 11 Civ. 8196 (CM)
Plaintiff, :
 : **NOVARTIS PHARMACEUTICALS**
v. : **CORPORATION’S ANSWER**
 :
NOVARTIS PHARMACEUTICALS :
CORPORATION, :
 :
Defendant. :
-----X

Defendant Novartis Pharmaceuticals Corporation (“Novartis”), for its Answer to the Complaint-In-Intervention of the United States of America (“Complaint”), dated April 19, 2013, which was filed by the United States of America, by its attorney, Preet Bharara, United States Attorney for the Southern District of New York (“Government” or “Plaintiff”), by its undersigned counsel, states as follows:

1. Denies the allegations set forth in numbered paragraph 1 of the Complaint, except admits that the Government purports to bring this civil action against Novartis under the False Claims Act, 31 U.S.C. §§ 3729-3733 (the “FCA”), and the common law.

2. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the second sentence of numbered paragraph 2 of the Complaint and denies the allegations set forth in the third sentence of numbered paragraph 2 of the Complaint. Because the first sentence of numbered paragraph 2 of the Complaint states conclusions or characterizations of law, no response is required.

3. Denies the allegations set forth in numbered paragraph 3 of the Complaint.

4. Denies the allegations set forth in numbered paragraph 4 of the Complaint.

5. Denies the allegations set forth in numbered paragraph 5 of the Complaint.

6. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the second sentence of numbered paragraph 6 of the Complaint, and denies the remaining allegations set forth in numbered paragraph 6 of the Complaint.

7. Because numbered paragraph 7 of the Complaint states conclusions or characterizations of law, no response is required.

8. Denies the allegations set forth in numbered paragraph 8 of the Complaint, except admits that Novartis markets and sells brand name prescription drugs within the geographic boundaries over which the United States District Court for the Southern District of New York presides. To the extent that numbered paragraph 8 of the Complaint states conclusions or characterizations of law, no response is required.

9. Admits the allegations set forth in numbered paragraph 9 of the Complaint.

10. Denies knowledge or information sufficient to form a belief as to the truth of what the Government alleges is “relevant here,” and otherwise admits the allegations set forth in numbered paragraph 10 of the Complaint.

11. Because numbered paragraph 11 of the Complaint states conclusions or characterizations of law, no response is required.

12. Admits that the AKS contains the language quoted in numbered paragraph 12 of the Complaint and respectfully refers the Court to 42 U.S.C. § 1320a-7b for the entire text. To the extent that numbered paragraph 12 of the Complaint states conclusions or characterizations of law, no response is required.

13. Admits that the “Special Fraud Alerts” contain the language quoted in numbered paragraph 13 of the Complaint and respectfully refers the Court to the Federal Register for the

entire text. To the extent that numbered paragraph 13 of the Complaint states conclusions or characterizations of law, no response is required.

14. Admits that the FCA contains the language quoted in numbered paragraph 14 and respectfully refers the Court to 31 U.S.C. §§ 3729-3733 for the entire text. To the extent that numbered paragraph 14 and footnote numbers 1 and 2 of the Complaint state conclusions or characterizations of law, no response is required.

15. Admits that the AKS contains the language quoted in numbered paragraph 15 of the Complaint and respectfully refers the Court to 42 U.S.C. § 1320a-7b for the entire text, and admits that the PPACA was not enacted until 2010. To the extent that numbered paragraph 15 of the Complaint states conclusions or characterizations of law, no response is required.

16. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 16 of the Complaint, except admits that Medicare is a federal program that provides coverage of some healthcare services for persons who are 65 or older or are disabled, and respectfully refers the Court to 42 U.S.C. §§ 1395 *et seq.* and related regulations for a description of the program. To the extent that numbered paragraph 16 of the Complaint states conclusions or characterizations of law, no response is required.

17. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 17 of the Complaint. To the extent that numbered paragraph 17 of the Complaint states conclusions or characterizations of law, no response is required.

18. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 18 of the Complaint, except admits that Medicaid is a joint federal-state program, and respectfully refers the Court to the relevant federal and state

statutes and regulations for a description of the program. To the extent that numbered paragraph 18 of the Complaint states conclusions or characterizations of law, no response is required.

19. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 19 of the Complaint. To the extent that numbered paragraph 19 of the Complaint states conclusions or characterizations of law, no response is required.

20. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 20 of the Complaint. To the extent that numbered paragraph 20 of the Complaint states conclusions or characterizations of law, no response is required.

21. Denies the allegations set forth in numbered paragraph 21 of the Complaint, except admits that Myfortic is a delayed-release antimetabolite immunosuppressant tablet indicated for prophylaxis of organ rejection in adult patients receiving kidney transplants and in pediatric patients at least 5 years of age and older who are at least 6 months post kidney transplant, to be used in combination with cyclosporine and corticosteroids.

22. Denies the allegations set forth in numbered paragraph 22 of the Complaint, except admits that, at times, various Novartis employees have negotiated rebate and discount contracts with pharmacies and transplant centers, promoted Myfortic to transplant physicians and created marketing materials for Myfortic.

23. Denies the allegations set forth in numbered paragraph 23 of the Complaint, except admits that Novartis makes Myfortic available for sale to pharmacies through wholesalers

and that pharmacies that dispense Myfortic to patients may submit reimbursement claims to the patients' insurers, including Medicare and Medicaid.

24. Denies the allegations set forth in numbered paragraph 24 and footnote 3 of the Complaint, except admits that certain Myfortic prescriptions may be eligible for reimbursement under Medicaid and/or Medicare Parts B and D, and respectfully refers the Court to 42 U.S.C. §§ 1396r-8 for a full and complete reading of its provisions. To the extent that numbered paragraph 24 and footnote number 3 of the Complaint state conclusions or characterizations of law, no response is required.

25. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the third sentence of numbered paragraph 25 of the Complaint, denies that the price of branded Cellcept and Myfortic were "generally comparable," and denies the allegations set forth in the first two sentences of numbered paragraph 25 of the Complaint, except admits that CellCept is a brand-name drug in the same therapeutic class as Myfortic and that generic versions of CellCept, which have been available since 2009, are generally priced lower than both branded CellCept and Myfortic.

26. Denies the allegations set forth in numbered paragraph 26 of the Complaint, except admits that certain contracts executed by Novartis provide a Medicare Part B Utilization Performance Benefit to pharmacies for achieving certain utilization benchmarks in relation to Myfortic, as specified therein.

27. Denies the allegations set forth in numbered paragraph 27 of the Complaint, except admits that a Novartis employee sent an e-mail on October 16, 2009 regarding contract negotiations with Bryant's Pharmacy, and respectfully refers the Court to that e-mail.

28. Denies the allegations set forth in numbered paragraph 28 of the Complaint, except admits that it has paid millions of dollars in rebates to state Medicaid agencies in connection with the dispensing of Myfortic to Medicaid patients over the time period referenced in the Government's Complaint.

29. Denies the allegations set forth in numbered paragraph 29 of the Complaint, except admits that a Novartis employee prepared a monthly report dated March 2010 regarding Twenty-Ten Pharmacy, and respectfully refers the Court to the report.

30. Admits that there exists Novartis Pharma Principles & Practices for Professionals that includes the language quoted in numbered paragraph 30, and respectfully refers the Court to that document for a full and complete reading of its content, and denies the remaining allegations set forth in numbered paragraph 30 of the Complaint.

31. Admits that Novartis Ethics and Compliance ("E&C") Policies contain the language quoted in numbered paragraph 31 and respectfully refers the Court to that document for a full and complete reading of its content.

32. Admits that Novartis's internal policies include Novartis E&C Policies that include the language quoted in numbered paragraph 32 and respectfully refers the Court to that document for a full and complete reading of its content, and denies the remaining allegations set forth in numbered paragraph 32 of the Complaint.

33. Admits that Novartis E&C Policies contain the language quoted in numbered paragraph 33 and respectfully refers the Court to that document for a full and complete reading of its content, and denies the remaining allegations set forth in numbered paragraph 33 of the Complaint.

34. Admits that Novartis has fully complied with the AKS and its own internal policies in connection with the sale, promotion and marketing of Myfortic, and is further unable to respond because the allegation lacks any information about the identities of the referenced executives.

35. Admits that, in September 2010, Novartis entered into a settlement agreement with the Government and several Relators to resolve civil claims brought by the Government, the Relators and certain states regarding Novartis's promotion of certain drugs and that Novartis entered into a separate plea agreement with the Government with respect to an information brought by the Government regarding Novartis's alleged off label promotion of one drug, and respectfully refers the Court to those documents for a full and complete reading of their content, and denies the remaining allegations set forth in numbered paragraph 35 of the Complaint.

36. Admits the allegations set forth in numbered paragraph 36 of the Complaint, and respectfully refers the Court to the Novartis CIA for a full and complete reading of its content.

37. Admits that the Novartis CIA contains the language quoted in numbered paragraph 37 of the Complaint and respectfully refers the Court to the Novartis CIA for a full and complete reading of its content.

38. Admits that the Novartis CIA includes various certification provisions and respectfully refers the Court to the Novartis CIA for a full and complete reading of its content, and denies the remaining allegations set forth in numbered paragraph 38 of the Complaint.

39. Admits that the Novartis CIA includes various notification provisions and respectfully refers the Court to the Novartis CIA for a full and complete reading of its content, and denies the remaining allegations set forth in numbered paragraph 39 of the Complaint.

40. Denies the allegations set forth in numbered paragraph 40 of the Complaint.

41. Denies the allegations set forth in numbered paragraph 41 of the Complaint.

42. Denies the allegations set forth in numbered paragraph 42 of the Complaint.

43. Denies the allegations set forth in numbered paragraph 43 of the Complaint.

44. Denies the allegations set forth in numbered paragraph 44 of the Complaint, except admits that, on January 29, 2010, a Novartis employee sent an e-mail to the director of the outpatient pharmacy at Baylor University Medical Center regarding Myfortic, and respectfully refers the Court to that e-mail.

45. Denies the allegations set forth in numbered paragraph 45 of the Complaint.

46. Denies the allegations set forth in numbered paragraph 46 of the Complaint.

47. Denies the allegations set forth in numbered paragraph 47 of the Complaint.

48. Denies the allegations set forth in numbered paragraph 48 of the Complaint.

49. Denies the allegations set forth in numbered paragraph 49 of the Complaint.

50. Denies the allegations set forth in numbered paragraph 50 of the Complaint.

51. Denies the allegations set forth in numbered paragraph 51 of the Complaint.

52. Denies the allegations set forth in numbered paragraph 52 of the Complaint.

53. Denies the allegations set forth in numbered paragraph 53 of the Complaint.

54. Denies the allegations set forth in numbered paragraph 54 of the Complaint.

55. Denies the allegations set forth in numbered paragraph 55 of the Complaint.

56. Denies the allegations set forth in numbered paragraph 56 of the Complaint.

57. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 57 of the Complaint.

58. Denies the allegations set forth in the first and third sentences of numbered paragraph 58 of the Complaint, and denies knowledge or information sufficient to form a belief

as to the truth of the allegations set forth in the second sentence of numbered paragraph 58 of the Complaint.

59. Denies the allegations set forth in numbered paragraph 59 of the Complaint, except admits that, on October 16, 2009, a Novartis employee sent an e-mail to other Novartis employees regarding Bryant's Pharmacy, and that, in December 2009, Novartis amended its June 1, 2007 agreement with Bryant's Pharmacy, effective October 1, 2009, and respectfully refers the Court to that e-mail and amendment.

60. Denies the allegations set forth in numbered paragraph 60 of the Complaint.

61. Denies the allegations set forth in numbered paragraph 61 of the Complaint.

62. Denies the allegations set forth in numbered paragraph 62 of the Complaint.

63. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the first sentence of numbered paragraph 63 of the Complaint and denies the allegations set forth in the second and third sentences of numbered paragraph 63 of the Complaint.

64. Denies the allegations set forth in numbered paragraph 64 of the Complaint.

65. Denies the allegations set forth in numbered paragraph 65 of the Complaint.

66. Denies the allegations set forth in numbered paragraph 66 of the Complaint.

67. Denies the allegations set forth in numbered paragraph 67 of the Complaint.

68. Denies the allegations set forth in numbered paragraph 68 of the Complaint.

69. Denies the allegations set forth in numbered paragraph 69 of the Complaint.

70. Denies the allegations set forth in numbered paragraph 70 of the Complaint.

71. Denies the allegations set forth in numbered paragraph 71 of the Complaint.

72. Denies the allegations set forth in numbered paragraph 72 of the Complaint.

73. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the first sentence of numbered paragraph 73 of the Complaint and denies the allegations set forth in the second sentence of numbered paragraph 73 of the Complaint.

74. Denies the allegations set forth in numbered paragraph 74 of the Complaint, except admits that, on March 22, 2011, Novartis received an e-mail from the President of Kilgore regarding Myfortic, and respectfully refers the Court to that e-mail.

75. Denies the allegations set forth in numbered paragraph 75 of the Complaint.

76. Denies the allegations set forth in numbered paragraph 76 of the Complaint.

77. Denies the allegations set forth in numbered paragraph 77 of the Complaint.

78. Denies the allegations set forth in numbered paragraph 78 of the Complaint.

79. Denies the allegations set forth in numbered paragraph 79 of the Complaint.

80. Denies the allegations set forth in numbered paragraph 80 of the Complaint.

81. Denies the allegations set forth in numbered paragraph 81 of the Complaint.

82. Denies the allegations set forth in numbered paragraph 82 of the Complaint.

83. Denies the allegations set forth in numbered paragraph 83 of the Complaint.

84. Denies the allegations set forth in numbered paragraph 84 of the Complaint.

85. Denies the allegations set forth in numbered paragraph 85 of the Complaint.

86. Denies the allegations set forth in the first sentence of numbered paragraph 86 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the second, third and fourth sentences of numbered paragraph 86 of the Complaint.

87. Denies the allegations set forth in numbered paragraph 87 of the Complaint.

88. Denies the allegations set forth in numbered paragraph 88 of the Complaint.

89. Denies the allegations set forth in numbered paragraph 89 of the Complaint.

90. Denies the allegations set forth in the first sentence of numbered paragraph 90 of the Complaint and denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the second and third sentences of numbered paragraph 90 of the Complaint.

91. Denies the allegations set forth in numbered paragraph 91 of the Complaint, except admits that, since 2004, Novartis has entered into certain agreements involving Twenty-Ten Pharmacy, and respectfully refers the Court to those agreements for a full and complete reading of their content.

92. Denies the allegations set forth in numbered paragraph 92 of the Complaint.

93. Denies the allegations set forth in numbered paragraph 93 of the Complaint.

94. Denies the allegations set forth in numbered paragraph 94 of the Complaint.

95. Denies the allegations set forth in numbered paragraph 95 of the Complaint.

96. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the first sentence of numbered paragraph 96 of the Complaint as to Twenty-Ten, and denies the allegations set forth in the second sentence of numbered paragraph 96 of the Complaint, except admits that, on April 5, 2010, a Novartis employee sent an e-mail to her supervisor regarding Twenty-Ten Pharmacy, and respectfully refers the Court to that e-mail.

97. Denies the allegations set forth in numbered paragraph 97 of the Complaint.

98. Denies the allegations set forth in numbered paragraph 98 of the Complaint.

99. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the first sentence of numbered paragraph 99 of the Complaint and denies

the allegations set forth in the second and third sentences of numbered paragraph 99 of the Complaint.

100. Denies the allegations set forth in the first sentence of numbered paragraph 100 of the Complaint and denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the second sentence of numbered paragraph 100 of the Complaint.

101. Denies the allegations set forth in numbered paragraph 101 of the Complaint.

102. Denies the allegations set forth in numbered paragraph 102 of the Complaint.

103. Denies the allegations set forth in numbered paragraph 103 of the Complaint.

104. Denies the allegations set forth in numbered paragraph 104 of the Complaint.

105. Denies the allegations set forth in numbered paragraph 105 of the Complaint.

106. Denies the allegations set forth in numbered paragraph 106 of the Complaint.

107. Denies the allegations set forth in numbered paragraph 107 of the Complaint, except admits that, on October 29, 2009, a Novartis employee sent an e-mail to several other Novartis employees regarding Myfortic contracting, and respectfully refers the Court to that e-mail.

108. Denies the allegations set forth in numbered paragraph 108 of the Complaint.

109. Denies the allegations set forth in numbered paragraph 109 of the Complaint.

110. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 110 of the Complaint and states that it has fully complied with the AKS and its own internal policies in connection with the sale, promotion and marketing of Myfortic. To the extent that numbered paragraph 110 of the Complaint states conclusions or characterizations of law, no response is required.

111. Denies the allegations set forth in numbered paragraph 111 of the Complaint.

112. Denies the allegations set forth in numbered paragraph 112 of the Complaint.

113. Denies the allegations set forth in numbered paragraph 113 of the Complaint.

114. Denies the allegations set forth in numbered paragraph 114 of the Complaint.

115. Denies the allegations set forth in numbered paragraph 115 of the Complaint.

116. Denies the allegations set forth in numbered paragraph 116 of the Complaint, except admits that, on February 25, 2011, a Novartis employee sent an e-mail to several other Novartis employees regarding Walgreen's, and respectfully refers the Court to that e-mail.

117. Denies the allegations set forth in numbered paragraph 117 of the Complaint, except admits that, on February 25, 2011, a Novartis employee sent an e-mail to several other Novartis employees regarding Walgreen's, and respectfully refers the Court to that e-mail.

118. Denies the allegations set forth in numbered paragraph 118 of the Complaint.

119. Denies the allegations set forth in numbered paragraph 119 of the Complaint, except admits that Novartis has internal policies regarding raising compliance concerns with the company, and respectfully refers the Court to those policies for a full and complete reading of their content.

120. Denies the allegations set forth in numbered paragraph 120 of the Complaint.

121. Denies the allegations set forth in numbered paragraph 121 of the Complaint.

122. Denies the allegations set forth in numbered paragraph 122 of the Complaint.

123. Denies the allegations set forth in numbered paragraph 123 of the Complaint.

FIRST CLAIM

Violations of the False Claims Act: Presenting False Claims for Payment (31 U.S.C. § 3729(a)(1) (2000), and, as amended, 31 U.S.C. § 3729(a)(1)(A))

124. Novartis repeats and incorporates by reference its responses to numbered paragraphs 1 through 123 above.

125. Because numbered paragraph 125 of the Complaint states conclusions or characterizations of law, no response is required.

126. Denies the allegations set forth in numbered paragraph 126 of the Complaint.

127. Denies the allegations set forth in numbered paragraph 127 of the Complaint.

128. Denies the allegations set forth in numbered paragraph 128 of the Complaint.

SECOND CLAIM

Violations of the False Claims Act: Use of False Statements (31 U.S.C. § 3729(a)(2) (2000) and, as amended, 31 U.S.C. § (a)(1)(B) (Supp. 2009))

129. Novartis repeats and incorporates by reference its responses to numbered paragraphs 1 through 123 above.

130. Because numbered paragraph 130 of the Complaint states conclusions or characterizations of law, no response is required.

131. Denies the allegations set forth in numbered paragraph 131 of the Complaint.

132. Denies the allegations set forth in numbered paragraph 132 of the Complaint.

133. Denies the allegations set forth in numbered paragraph 133 of the Complaint and respectfully refers the Court to 31 U.S.C. § 3729(a)(1)(B) for a full and complete reading of its provisions. To the extent that numbered paragraph 131 of the Complaint states conclusions or characterizations of law, no response is required.

134. Denies the allegations set forth in numbered paragraph 134 of the Complaint.

THIRD CLAIM

Violations of the False Claims Act: Conspiring to Violate the False Claims Act (31 U.S.C. § 3729(a)(3) (1986) and, as amended, 31 U.S.C. § 3729(a)(1)(C))

135. Novartis repeats and incorporates by reference its responses to numbered paragraphs 1 through 123 above.

136. Because numbered paragraph 136 of the Complaint states conclusions or characterizations of law, no response is required.

137. Denies the allegations set forth in numbered paragraph 137 of the Complaint.

138. Denies the allegations set forth in numbered paragraph 138 of the Complaint.

139. Denies the allegations set forth in numbered paragraph 139 of the Complaint.

FOURTH CLAIM

Unjust Enrichment

140. Novartis repeats and incorporates by reference its responses to numbered paragraphs 1 through 123 above.

141. Denies the allegations set forth in numbered paragraph 141 of the Complaint.

142. Denies the allegations set forth in numbered paragraph 142 of the Complaint.

143. Denies the allegations set forth in numbered paragraph 143 of the Complaint.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

The Government fails to state a claim against Novartis upon which relief may be granted, and the Complaint should be dismissed.

SECOND AFFIRMATIVE DEFENSE

The Government fails to allege any false claim under the False Claims Act because Novartis's conduct did not result in any "false or fraudulent claim" in violation of 31 U.S.C. § 3729(a).

THIRD AFFIRMATIVE DEFENSE

The Government's claims fail because the rebate payments and discounts at issue are not unlawful kickbacks under 42 U.S.C. § 1320a-7b.

FOURTH AFFIRMATIVE DEFENSE

The rebate payments and discounts at issue are protected under the statutory exception for discounts provided for in 42 U.S.C. § 1320a-7b(b)(3)(A).

FIFTH AFFIRMATIVE DEFENSE

The rebate payments and discounts at issue are protected under the regulatory exceptions (safe harbors) for discounts provided for in 42 C.F.R. § 1001.952(h).

SIXTH AFFIRMATIVE DEFENSE

The Government's claims are barred because, at all times relevant hereto, Novartis complied with all applicable federal and state regulations.

SEVENTH AFFIRMATIVE DEFENSE

The Government's claims are barred, in whole or in part, because they rely upon ambiguous provisions of the False Claims Act and other provisions of law, and the rule of lenity requires such ambiguities to be construed in Novartis's favor.

EIGHTH AFFIRMATIVE DEFENSE

The Government's claims are barred, in whole or in part, because they violate Novartis's rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, insofar as the Government seeks to impose liability retroactively for conduct that is not prohibited by federal statutes or regulations.

NINTH AFFIRMATIVE DEFENSE

Any and all actions taken by Novartis with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

TENTH AFFIRMATIVE DEFENSE

The Government's claims are barred, in whole or in part, due to its failure to join indispensable parties.

ELEVENTH AFFIRMATIVE DEFENSE

The Government's claims are barred, in whole or in part, by the applicable statutes of limitations and repose.

TWELFTH AFFIRMATIVE DEFENSE

The Government's claims are barred, in whole or in part, by the doctrine of consent and/or ratification to the extent that the Government, through the Medicare and Medicaid programs, has reimbursed specialty pharmacy providers for dispensing Myfortic to Medicare and Medicaid beneficiaries after the filing of the Complaint.

THIRTEENTH AFFIRMATIVE DEFENSE

The Government's claims are barred, in whole or in part, by the doctrines of laches, estoppel and waiver.

FOURTEENTH AFFIRMATIVE DEFENSE

The Government's claims for damages are barred or should be reduced based on the Government's failure to mitigate damages.

FIFTEENTH AFFIRMATIVE DEFENSE

To the extent that the Government attempts to seek equitable relief against Novartis, it is not entitled to such relief because it has an adequate remedy at law.

SIXTEENTH AFFIRMATIVE DEFENSE

To the extent civil penalties are sought against Novartis, such civil penalties cannot be sustained because an award of civil penalties would violate the Excessive Fines Clause of the Eighth Amendment and the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution.

SEVENTEENTH AFFIRMATIVE DEFENSE

To the extent that the Government is alleging fraud or similar conduct, it has failed to plead fraud with particularity.

EIGHTEENTH AFFIRMATIVE DEFENSE

The Government's federal common law unjust enrichment claims are displaced by statute.

NINETEENTH AFFIRMATIVE DEFENSE

The Government's claims are too remote and speculative to form the basis for relief.

TWENTIETH AFFIRMATIVE DEFENSE

The Government has not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Novartis as alleged in the Complaint.

TWENTY-FIRST AFFIRMATIVE DEFENSE

The Government's claims are barred in whole or in part, because the Government's injuries were not proximately caused by the acts or omissions of Novartis, but, if they exist at all, were the result in whole or in part of intervening or supervening causes.

TWENTY-SECOND AFFIRMATIVE DEFENSE

To the extent the Government obtains or obtained recovery in any other proceeding predicated on the same factual allegations, the Government is barred from seeking recovery against Novartis based on the Complaint pursuant to the doctrines of res judicata and collateral estoppel, and the prohibition on double recovery for the same injury.

TWENTY THIRD AFFIRMATIVE DEFENSE

Novartis reserves the rights to raise any additional defenses, cross-claims and third party claims not asserted herein of which it may become aware through discovery or other investigation.

PRAYER FOR RELIEF

WHEREFORE, Novartis Pharmaceuticals Corporation prays as follows:

That all claims contained in the Government's Complaint against it be dismissed with prejudice.

That it be awarded costs and attorneys' fees.

That it have such other and further relief as this Court deems just and proper.

Dated: New York, New York
June 28, 2013

Respectfully submitted,

s/Manvin Mayell

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